Attorney's Docket No.: 17315-002001

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: St. Goar et al.

Art Unit: 3732

Serial No.: 10/635,776

Examiner: Cary O'Connor

Filed

: August 5, 2003

Conf. No.: 1704

Title

: METHODS AND APPARATUS FOR CARDIAC VALVE REPAIR

## Mail Stop Amendment

Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

## TRANSMITTAL LETTER

Dear Sir:

Transmitted herewith are a Supplemental Information Disclosure Statement, Form PTO-1449 (4 pages), cited non U.S. patent references, and return postcard for filing in connection with the above-captioned patent application.

The Commissioner is hereby authorized to charge the fee for the extension of time and any other fee that may be due in connection with this and the attached papers or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

September 19, 2005

Respectfully submitted,

Fred C. Hernandez Reg. No. 41,832

PTO Customer No.: 20985 Fish & Richardson P.C. 12390 El Camino Real San Diego, California 92130 Telephone: (858) 678-5625

Facsimile: (202) 626-7796 Email: fhernandez@fr.com

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

	September 19, 2005	
Date of Deposit,		
46	Lly U. Smith	
Signature		
	Kelly M. Smith	

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## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN ACCORDANCE WITH 37 C.F.R. §§1.97-1.98

Dear Sir:

Because this Supplemental Information Disclosure Statement is filed before the receipt of a First Office Action on the Merits for the above-captioned application, a fee for filing this statement should not be due. If, however, it is determined that a fee is due, any fees that may be due in connection with filing this paper may be charged to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Form PTO-1449 (4 pages) and copies of the Foreign Patents and Non-Patent Literature are provided herewith in connection with the above-captioned application.

The documents listed on the Form PTO-1449 are in the English language with the exception of items BF, CC and CH. Item BF (Gateliene et al.) is in the Lithuanian language and is supplied with an English language summary attached to the article. Items CC and CH (Nakanishi et al. and Tamura et al., respectively) are in the Japanese language and are provided with English language summaries attached to the article. Hence, in accordance with

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I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

	September 19, 2005	
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	Kelly M	8mith
Signature		
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Applicant: St. Goar et al.

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Attorney's Docket No.: 17315-002001

Supplemental Information Disclosure Statement

Filed : August 5, 2003

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the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed item is necessary.

Applicant also makes known to the Examiner the following pending U.S. and International Applications that have one or more common inventors and/or are commonly owned:

<u>U.S.S.N.</u>	Filing Date	Publication No.	Docket No.
09/894,463	06/27/01	2002/0013571	020489-000400US
10/087,004	03/01/02	2003/0167071	20489-000500US
10/202,599	07/24/02	2002/0183766	20489-000310US
10/441,508	05/19/03	2004/0092962	20489-001500US
10/441,531	05/19/03	2004/0049207	20489-001400US
10/441,687	05/19/03	2004/0087975	20489-001700US
10/441,753	05/19/03	2004/0044350	20489-001200US
10/613,443	07/03/03	2004/0003819	20489-000120US
10/638,022	08/07/03	2004/0039442	20489-000130US
10/803,444	03/17/04	2004/0225300	20489-000410US
10/820,581	04/07/04	2005/0033446	17315-002002
10/877,279	06/24/04	2004/0236354	020489-000330US
10/927,263	08/25/04	2005/0021056	020489-000160US
10/927,589	08/25/04	2005/0021057	020489-000150US
60/650,918	02/07/05	n/a	17315-004P01
11/058,957	02/15/05	2005/0149014	020489-001830US
60/674,931	04/25/05	n/a	17315-005P01
60/692,802	06/21/05	n/a	17315-004P02

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

Applicant: St. Goar et al. Serial No.: 10/635,776 Filed

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Applicant respectfully requests that the Examiner review the foregoing references and make them of record in the file history of the above-captioned application.

Respectfully submitted,

Attorney's Docket No.: 17315-002001

Supplemental Information Disclosure Statement

September 19, 2005

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Substitute Form PTO-1449

U.S. Department of Commerce Patent and Trademark Office Attorney's Docket No. 17315-002001

Application No. 10/635,776

# List of Patents and Publications for Applicant's Information Disclosure Statement

Applicant St. Goar et al.

Filing Date
August 5, 2003

Group Art Unit 3732

(37 CFR §1.98(b))

**U.S. Patent Documents** Examiner Desig. Document Publication Filing Date Initial Number Date Patentee Class If Appropriate ID Subclass **Downing** 2002/0161378 10/31/02 606 06/15/01 AA108 2002/0183835 12/05/02 Taylor et al. 2.11 02/05/02 AB 623 Fasol et al. AC 2003/0105519 06/05/03 623 2.1 09/04/98 Schreck AD 2003/0187467 10/02/03 606 150 03/26/02 ΑE 2004/0097979 05/20/04 Svanidze et al. 606 151 11/14/02 AF 2004/0158123 08/12/04 Jayaraman 600 37 02/02/04 AG 2004/0236354 11/25/04 Seguin, J. 606 139 06/24/04 ΑH 5,769,863 06/23/98 Garrison 606 148 12/16/96 ΑI 6,575,971 06/10/03 Hauck et al. 606 52 11/15/01 ΑJ 6,626,930 09/30/03 Allen et al. 606 213 05/01/00

	Foreign Patent Documents or Published Foreign Patent Applications							
Examiner	Desig.	Document	Publication	Country or			Trans	slation
Initial	ID	Number	Date	Patent Office	Class	Subclass	Yes	No
	AK	03/001893	01/09/03	PCT				
	AL	03/073913	09/12/03	PCT				
	AM	04/112585	12/29/04	PCT				
	AN	04/112651	12/29/04	PCT				
	AO	05/032421	04/14/05	PCT				
	AP	05/062931	07/14/05	PCT				

	Other Documents (include Author, Title, Date, and Place of Publication)			
Examiner	Desig.			
Initial	ID	Document		
	AQ	Agricola et al., "Mitral valve reserve in double orifice technique: an exercise echocardiographic study," Journal of Heart Valve Disease 11(5): 637-643 (2002)		
	AR Alfieri et al., "An effective technique to correct anterior mitral leaflet prolapse," J. Card. Surg. 14(6): 468-470 (1999)			
	AS	Alfieri et al., "Novel suture device for beating heart mitral leaflet approximation," Annals of Thoracic Surgery 74: 1488-1493 (2002)		
	AT	Alfieri et al., "The double orifice technique in mitral valve repair: a simple solution for complex problems," Journal Of Thoracic Cardiovascular Surgery 122: 674-681 (2001)		

**Examiner Signature** 

Date Considered

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute For (Modified)	m PTO-1449	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 17315-002001	Application No. 10/635,776	
List of Patents and Publications for Applicant's Information Disclosure Statement			Applicant St. Goar et al.		
(37 CFR §1.98	(b))	•	Filing Date August 5, 2003	Group Art Unit 3732	
(	Other Do	ocuments (include Author, 1	Fitle, Date, and Place of	f Publication)	
Examiner Initial	Desig. ID	Document			
	AU	Alfieri, O., "Surgical Treatment of At to-edge repair of the mitral valve," [A Technology, Heart Surgery Forum, pp	bstract] 6th Annual NewEra Car o. 103 (2003)	diac Care: Innovation &	
	AV	Alfieri, O., "The edge-to-edge repair Care: Innovation & Technology, Hear	t Surgery Forum, pp. 103 (2003)	)	
	AW	Arisi et al., "Mitral valve repair with a early echocardiographic results," Circ	ulation Supplement II, 104: 324	0 (2001)	
	AX	Bhudia, S., "Edge-to-edge mitral repa Foundation, Cleveland, Ohio, <a href="http://w">http://w</a>	ww.ctsnet.org/doc/7007 (access	ed on December 14, 2004)	
	AY	Borghetti et al., "Preliminary observat following 'double-orifice' mitral valve 262-269 (2001)	e repair," European Journal of C	ardio-thoracic Surgery 20:	
	AZ	Castedo, "Edge-to-edge tricuspid repair for redeveloped valve incompetence after DeVega's annuloplasty," Ann Thora Surg. 75: 605-606 (2003)			
	BA	Dottori et al., "Echocardiographic imaging of the Alfieri type mitral valve repair," Ital. Heart J. 2(4): 319-320 (2001)			
	BB	Downing et al., "Beating heart mitral valve surgery: preliminary model and methodology," Journal of Thoracic and Cardiovascular surgery 123(6): 1141-1146 (2002)			
	ВС	Falk et al., "Computer-enhanced mitral valve surgery: toward a total endoscopic procedure," Seminars in thoracic and cardiovascular surgery 11(3): 224-249 (1999)			
	BD	Fundarò et al., "Chordal placation and repair: 8 year follow-up," Annals of T	horacic Surgery 72: 1515-1519	(2001)	
	BE	Garcia-Rinaldi et al., "Left ventricular cardiomyopathy," Journal of Cardiac	Surgery 14: 199-210 (1999)		
	BF	Gatelienė, "Early and postoperative re treatment using edge-to-edge central of [Article in Lithuanian, English summa	coaptation procedure," Medicina ary on page 174 of the article	38 (Suppl 2): 172-175 (2002)	
	BG	Gatti et al., "The edge to edge techniq repair," Eur. J. Cardiothorac Surg 22(	5): 817-20 (2002)	•	
	ВН	Gillinov et al., "Is minimally invasive heart valve surgery a paradigm for future?" Current Cardiology Reports 1: 318-322 (1999)			
	BI	Gundry et al., "Facile Minimally Invasive Cardiac Surgery via Ministernotomy," Ann. Thorac. Surg. 65: 1100-1104 (1998)			
	ВЈ	Ikeda et al., "Batista's operation with coronary artery bypass grafting and mitral valve plasty for ischemic dilated cardiomyopathy," The Japanese Journal of Thoracic and Cardiovascular Surgery 48: 746-749 (2000)			
	ВК	Izzat et al., "Early experience with pa of Thoracic Surgery 67: 1703-1707 (1	999)		
	BL	Källner et al., "Transaortic approach f		. ,	
	ВМ	Kavarna et al., "Transaortic repair of Cardiac Care conference, San Diego, <a href="http://www.hsforum.com/vol3/issue1/">http://www.hsforum.com/vol3/issue1/</a>	CA, January 13-16 (2000),		
		<del></del>			

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Examiner Initial	Desig. ID		Document	
	BN	Kaza et al., "Ventricular reconstruction of mitral insufficiency," Annals of Su	on results in improved left ventric rgery 235(6): 828-832 (2002)	cular function and amelioration
	во	Kherani, "The edge-to-edge mitral val Thorac. Surg. 78: 73-76 (2004)	•	
	BP	Konertz et al., "Results after partial le Journal of Cardiac Surgery 14(2): 129	)-135 (1999)	• • •
	BQ	Kron et al., "Surgical relocation of the regurgitation," Annals. of Thoracic Su	urgery 74: 600-601 (2002)	
	BR	Krüger et al., "Edge to edge technique (Supplement I): page 106 (abstract p7	3) (2000)	Ç
	BS	Lorusso et al., "'Double-Orifice' tech endocarditis," J. Card Surg 13: 24-26	(1998)	
	ВТ	Lorusso et al., "The double-orifice tec postoperative outcome," Eur J. Cardio		
	BU	Maisano et al., "The double orifice repair for Barlow Disease: a simple solution for a complex repair," Circulation (Supplement 1) 100(18): I-94 (1989)		
	BV	Maisano et al., "The double orifice technique as a standardized approach to treat mitral regurgitation due to severe myxomatous disease: surgical technique," European Journal of Cardiothoracic Surgery 17: 201-205 (2000)		
	BW	Maisano et al., "The hemodynamic effects of double-orifice valve repair for mitral regurgitation: a 3D computational model: a 3D computational model," European Journal of Cardio-thoracic Surgery 15: 419-425 (1999)		
	BX	Maisano et al., "Valve repair for traun 867-873 (1996)		
	BY	Mantovani et al., "Edge-to-edge repai Heart Valve Dis., 9(5): 641-643 (2000)	0)	. ,
	BZ	McCarthy et al., "Partial left ventricul failure," European Journal of Cardio-	thoracic Surgery 13: 337-343 (1	998)
	CA	Moainie et al., "Correction of traumat Annals of Thoracic Surgery 73: 963-9		he double orifice technique, "
	СВ	Morales et al., "Development of an of #1999-4693," 2(2): 115-120 (1999)	f bypass mitral valve repair," Th	ne Heart Surgery Fourm
	CC	Nakanishi et al., "Early outcome with the Alfieri mitral valve repair," J. Cardiol. 37(5): 263-266 (2001) [Abstract in English; Article in Japanese]		
	CD	Nielsen et al., "The edge-to-edge mitral repair: tension of the approximating suture and leaflet deformation during acute ischemic mitral regurgitation in the ovine heart," Circulation 104(Suppl 1): I-29-I-35 (2001)		
	CE	Osawa et al., "Partial left ventriculect Japanese Journal of Thoracic and Car		
	CF	Privitera et al., "Alfieri Mitral Valve I (2002)	Repair: Clinical Outcome and Pa	athology," Circulation 106: 173
	CG	Redaelli et al., "A computational stud repair," Journal of Biomechanical Eng		lge-to-edge' mitral valve

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(37 CFR §1.98	3(b))		August 5, 2003	3732
Other Documents (include Author, T			Fitle, Date, and Place o	f Publication)
Examiner	Desig.			
Initial	ID	Document		
	CH	Tamura et al., "Edge to edge repair for mitral regurgitation on a patient with chronic hemodialysis: report of a case," Kyobu Geka 54(9): 788-790 (2001) [Article in Japanese, English Summary]		
	CI	Timek, "Edge-to-edge mitral repair: gradients and three-dimensional annular dynamics in vivo during inotropic stimulation," European Journal of Cardio-thoracic Surgery 19: 431-437 (2001)		
	CJ	Timek, "Edge-to-edge mitral valve repair without ring annuloplasty for acute ischemic mitral regurgitation," Circulation 108 (Supplement II): II-122—II-127 (2003)		
	CK	Totaro, "Mitral valve repair for isolated prolapse of the anterior leaflet: an 11-year follow-up," European Journal of Cardio-thoracic Surgery 15: 119-126 (1999)		
	CL	Votta et al., "3-D computational analysis of the stress distribution on the leaflets after edge-to-edge repair of mitral regurgitation," Journal of Heart Valve Disease 11: 810-822 (2002)		

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